

## Minimizing FDA Compliance Risk

*Learn from the expert, Larry Spears has retired from the FDA and his services are available as an industry consultant:*

**Larry Spears** has recently retired from the FDA after 8 years as a Deputy Director for the Office of Compliance, 11 years experience as a field investigator and over 25 years experience with the FDA. He has significant compliance experience in managing regulatory actions including policy development, Warning Letters and enforcement case processing, and recall classification.

Interested in learning from the expert the real mindset and expectations of the FDA Office of Compliance? Concerned about compliance risk for your company and how to prevent compliance actions? Larry can teach you the real FDA perspective. Larry Spears Compliance Training includes:

- How to interpret letters from the Office of Compliance
- How the FDA evaluates responses and makes compliance decisions
- Strategies used by the Office of Compliance to define “for cause” company inspections
- What are inspectors trained to look for and what data are they asked to collect during inspections
- What are the key issues to be addressed in FDA responses
- How to better prepare for and better manage inspections

Are your management reviews ineffective in driving quality system improvement? Does your executive management really understand the intent of the Quality System Regulation? Larry can share with you how best in class manufacturers have achieved quality system compliance while enhancing the quality of the devices they produce. Larry Spears Quality System Effectiveness Training includes:

- Understanding the real cost of “non-compliance”
- Analyzing CAPA trends
- Evaluating design control effectiveness
- Tracking production process quality
- Driving quality improvement through management review

Other services offered by Larry Spears:

- Consulting for responding to FDA compliance actions
- Quality system audits

Call Certified Compliance Solutions at (858) 675-8200 for more information or visit our web site at [www.certifiedcomplaine.com](http://www.certifiedcomplaine.com).